

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

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| <b>IN RE: ETHICON, INC. PELVIC REPAIR<br/>SYSTEMS PRODUCTS LIABILITY<br/>LITIGATION</b>  | <b>Master File No. 2:12-MD-02327<br/>MDL 2327</b> |
| <b>THIS DOCUMENT RELATES TO:<br/>ALL WAVE II TVT-O CASES<br/>IDENTIFIED IN EXHIBIT A</b> | <b>JOSEPH R. GOODWIN<br/>U.S. DISTRICT JUDGE</b>  |

**REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION  
TO EXCLUDE THE TESTIMONY OF DR. MAREENI STANISLAUS**

Plaintiffs submit the following reply to Ethicon's Opposition to Plaintiffs' Motion to Exclude Dr. Mareeni Stanislaus.<sup>1</sup> For the following reasons, Ethicon's opposition should be denied and the opinions offered by Dr. Stanislaus should be excluded or limited in the Court's discretion as set forth in whole in Plaintiffs Motion to Exclude.<sup>2</sup>

**ARGUMENT**

**I. Dr. Stanislaus's opinions must be excluded to the extent that they are grounded in a selective review of the relevant scientific literature.**

As stated in Plaintiffs' original brief, this Court has previously held that expert witnesses may not ground their opinions in merely a selective review of academic or scientific literature, choosing only materials that support their opinions, while ignoring literature that does not.<sup>3</sup> This Court has noted that "[a]n expert's opinion may be unreliable if he fails to account for contrary

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<sup>1</sup> Future references to the Ethicon Brief will be in the form "Ethicon Memo, at \_\_\_\_).

<sup>2</sup> To the extent that Plaintiffs do not specifically reply to an argument in Ethicon's Memo, Plaintiffs incorporate their initial Memo by reference.

<sup>3</sup> Plaintiffs' Memo at 5-6 (citing *Winebarger v. Boston Sci. Corp.*, No. 2:13-cv-28892 2015 U.S. Dist. LEXIS 53892, at \*22).

scientific literature and instead selectively [chooses] his support from the scientific landscape.”<sup>4</sup> For example, in *Tyree*, this Court excluded Plaintiffs’ expert Dr. Margolis’s opinion regarding the complication rates of pain in women with polypropylene because he did not consider contrary studies showing lower complication rates.<sup>5</sup> Likewise, Dr. Stanislaus engaged in a selective review of the available scientific literature to support her opinion regarding the complications rates of the TVT-O device in this case. As discussed in Plaintiffs’ initial brief, Dr. Stanislaus’s selection of literature in this case neglected to include a 2011 peer-reviewed study by Teo, et al. which found significantly more leg pain in the TVT-O group of the study compared to the TVT-R group in the study.<sup>6</sup> Moreover, this study was stopped early because of the high leg pain complications in the TVT-O group, in comparison to the TVT-R group.<sup>7</sup> Dr. Stanislaus conceded that at the time she wrote her report in this case, she was not familiar with this study.<sup>8</sup> Dr. Stanislaus has not provided an adequate explanation for why she disagrees with the findings of the Teo, et al. study, other than to say, when questioned by Ethicon’s attorney, that this peer-reviewed study from the Journal of Urology must be a lower “level evidence” than the studies she has cited in her report.<sup>9</sup>

Seeking to direct the Court’s attention away from the lack of reliability of Dr. Stanislaus’s opinions, Ethicon dismisses the Teo, et al. study, which Dr. Stanislaus was

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<sup>4</sup> *Tyree v. Boston Sci. Corp.*, 54 F. Supp.3d 501, 520 (S.D. W. Va. 2014) (internal citations omitted). Ethicon’s citation to *Trevino v. Boston Scientific* to suggest that “[i]f there are certain-device specific publications that [an expert] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination” is unavailing in this case. Ethicon’s Memo at 11-12 (citing *Trevino v. Boston Sci. Corp.*, 2106 U.S. Dist. LEXIS 65967 (S.D. W. Va. May 19, 2016)). In *Trevino*, Plaintiffs broadly argued that Dr. Badylak did not review sufficient literature specific to the defendants’ devices. Here, Plaintiffs argue that Dr. Stanislaus’s selective review of the literature discounted contrary literature.

<sup>5</sup> *Id.* 521.

<sup>6</sup> Plaintiffs’ Memo at 5-6.

<sup>7</sup> Ex. B, at 106:22-25

<sup>8</sup> *Id.* at 107:19-24.

<sup>9</sup> *Id.* at 146: 13-18; *See Winebarger v. Boston Sci. Corp.*, No.2:13-cv-28892 2015 U.S. Dist. LEXIS 53892, at \*24 (noting that an expert’s methodology may be flawed if he does not provide an adequate explanation for why he disagrees with contrary studies).

unfamiliar with, as not being “Level 1” evidence.<sup>10</sup> Moreover, Ethicon even admits in their Response that Dr. Stanislaus “discounts the Teo study as compared to Level-1 evidence.”<sup>11</sup> Ethicon’s suggestion that Dr. Stanislaus “discounted” this study is not supported by Dr. Stanislaus’s own testimony, in which she testified that she was not familiar with the study at the time she wrote her report.<sup>12</sup> Moreover, Dr. Stanislaus testified that she would “need to read this more carefully to find out why they chose to study it—to stop it because of leg pain.”<sup>13</sup> It is clear that Dr. Stanislaus didn’t intentionally chose to not include this study in favor of other studies. Rather, her selective review of the literature left her unfamiliar with this study.

Ethicon’s defense of Dr. Stanislaus suggests that she relied only on “larger meta-analyses and systematic reviews” and that this therefore renders her literature selection reliable.<sup>14</sup> In this case, Dr. Stanislaus confined the selection of literature used to support her opinions to what she defines as “Level 1” data.<sup>15</sup> In confining her literature selection to what she considers to be a certain type of data, Dr. Stanislaus’s review of literature did not account for a published, peer-reviewed, study which was a direct comparison between the two products Dr. Stanislaus discusses in her report in this case and which would clinically significant differences between the two products.<sup>16</sup> The fact that Dr. Stanislaus’s literature selection did not include the Teo, et al. study is more than just fodder for cross-examination. Her lack of knowledge of this peer-reviewed, direct comparison between the TVT-R and TVT-O products she discusses makes it clear that her literature selection in this case does not provide a reliable methodology for her

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<sup>10</sup> Ethicon’s Memo at 11-12.

<sup>11</sup> *Id.* at 12.

<sup>12</sup> Ex. B, 107:19-23.

<sup>13</sup> Ex. B, 106: 22-107:15.

<sup>14</sup> Ethicon’s Memo at 5-6.

<sup>15</sup> Ethicon’s Memo at 7-8.

<sup>16</sup> Ex. B, 104:19-107:23.

opinions. Dr. Stanislaus's opinions regarding the safety and complication rates of the TVT-O device are not based on a reliable literature selection and should be excluded.

**II. Ethicon has not provided any information showing that Dr. Stanislaus should be permitted to opine on the topic of polypropylene degradation.**

Ethicon has failed to demonstrate that Dr. Stanislaus has used a proper methodology to reach a reliable conclusion regarding polypropylene degradation. In defense of Dr. Stanislaus's opinion that the mesh in the TVT-O does not experience any clinically significant degradation, Ethicon points out that Dr. Stanislaus has not seen evidence of degradation in her practice.<sup>17</sup> Ethicon's argument is undercut by Dr. Stanislaus's deposition testimony, which reveals that she has not taken any steps to actually study any potential degradation in her practice.<sup>18</sup> Dr. Stanislaus has never looked at a polypropylene mesh under a microscope, nor has she discussed degradation with a pathologist.<sup>19</sup> Dr. Stanislaus's statements, such as that she hasn't asked pathologists about degradation because "that hasn't really been a question I would think to ask," reveal a lack of experience—and suggest a lack of interest—in the topic of polypropylene degradation.<sup>20</sup> In a further attempt to suggest that Dr. Stanislaus may have some experience with degradation, Ethicon points to her statement that "I have patients now that I have been seeing since 2002, and their meshes are still in place. So [I] presume that they are still working without degradation."<sup>21</sup> The fact that Dr. Stanislaus can point to some of her patients whose meshes are still in place, is simply not reliable evidence that degradation of polypropylene mesh does not have clinical significance.

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<sup>17</sup> Ethicon's Memo at 14.

<sup>18</sup> See Plaintiffs' Memo at 9-10.

<sup>19</sup> Ex. B, 78:7-17; see Winebarger, U.S. Dist. LEXIS 53892, at \*101 (excluding the opinions of Dr. Culligan regarding the physical properties of polypropylene mesh, in part because his clinical experience lacked experience examining mesh under a microscope or discussing degradation with a pathologist).

<sup>20</sup> Ex. B, 78:11-17.

<sup>21</sup> Ex. B, 77:6-9.

**III. Dr. Stanislaus did not reliably acknowledge the differences between the TVT-O and TVT-R devices.<sup>22</sup>**

In its Response, Ethicon attempts to defend Dr. Stanislaus's opinions by suggesting that "Plaintiffs are now contending that the inherent characteristics of polypropylene mesh have nothing to [do] with the 'clinical safety' of the TVT-O."<sup>23</sup> This is a complete misrepresentation. In the language Ethicon cites to in Plaintiffs' Memo, Plaintiffs simply point out that Dr. Stanislaus acknowledges different clinical morbidities between the TVT-R and TVT-O devices that she sees in her practice, and yet she combines the data from these two clinically different devices in her report.<sup>24</sup>

**CONCLUSION**

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Stanislaus is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and her testimony should be excluded.

Dated: August 25, 2016

By: /s/ Edward A. Wallace  
Edward A. Wallace  
Mark R. Miller  
Timothy E. Jackson  
Wexler Wallace LLP  
55 W Monroe Street, Suite 3300  
T. (312) 346-2222  
F. (312) 346-0022  
E. eaw@wexlerwallace.com  
mrm@wexlerwallace.com  
tej@wexlerwallace.com

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<sup>22</sup> Plaintiffs' Memo Argument IV, p.6-7 is incorporated by reference.

<sup>23</sup> Ethicon's Memo at 7.

<sup>24</sup> Plaintiffs' Memo at 7.

**CERTIFICATE OF SERVICE**

I hereby certify that on August 25, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace